

§ 610.1

Subpart E—Testing Requirements for Communicable Disease Agents

- 610.40 Test requirements.
- 610.41 Donor deferral.
- 610.42 Restrictions on use for further manufacture of medical devices.
- 610.44 Use of reference panels by manufacturers of test kits.
- 610.46 “Lookback” requirements.
- 610.47 “Lookback” notification requirements for transfusion services.

Subpart F—Dating Period Limitations

- 610.50 Date of manufacture.
- 610.53 Dating periods for licensed biological products.

Subpart G—Labeling Standards

- 610.60 Container label.
- 610.61 Package label.
- 610.62 Proper name; package label; legible type.
- 610.63 Divided manufacturing responsibility to be shown.
- 610.64 Name and address of distributor.
- 610.65 Products for export.
- 610.67 Bar code label requirements.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

SOURCE: 38 FR 32056, Nov. 20, 1973, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see parts 124 and 125 of the Domestic Mail Manual, that is incorporated by reference in 39 CFR part 111.

Subpart A—Release Requirements

§ 610.1 Tests prior to release required for each lot.

No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies. The results of all tests performed shall be considered in determining whether or not the test results meet the test objective, except that a test result may be disregarded when it is established

21 CFR Ch. I (4–1–07 Edition)

that the test is invalid due to causes unrelated to the product.

§ 610.2 Requests for samples and protocols; official release.

(a) *Licensed biological products regulated by CBER.* Samples of any lot of any licensed product together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Center for Biologics Evaluation and Research (see mailing addresses in § 600.2 of this chapter). Upon notification by the Director, Center for Biologics Evaluation and Research, a manufacturer shall not distribute a lot of a product until the lot is released by the Director, Center for Biologics Evaluation and Research: *Provided*, That the Director, Center for Biologics Evaluation and Research, shall not issue such notification except when deemed necessary for the safety, purity, or potency of the product.

(b) *Licensed biological products regulated by CDER.* Samples of any lot of any licensed product together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2) for official release. Upon notification by the Director, Center for Drug Evaluation and Research, a manufacturer shall not distribute a lot of a biological product until the lot is released by the Director, Center for Drug Evaluation and Research: *Provided*, That the Director, Center for Drug Evaluation and Research shall not issue such notification except when deemed necessary for the safety, purity, or potency of the product.

[40 FR 31313, July 25, 1975, as amended by 49 FR 23834, June 8, 1984; 50 FR 10941, Mar. 19, 1985; 55 FR 11013 and 11014, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002; 70 FR 14984, Mar. 24, 2005]

Subpart B—General Provisions

§ 610.9 Equivalent methods and processes.

Modification of any particular test method or manufacturing process or the conditions under which it is conducted as required in this part or in the